REMARKS

Claims 63-127 were pending. Claims 63 and 66-93 have been canceled without prejudice. Claims 64, 65, 102, 105-109 and 111-127 have been withdrawn as directed to non-elected subject matter. Claim 94 has been amended. After entry of the instant amendment, Claims 94-101, 103, 104 and 110 will be pending and under consideration.

I. AMENDMENTS TO THE CLAIMS

Claims 63 and 66-93 have been canceled without prejudice.

Claims 64, 65, 102, 105-109 and 111-127 have been withdrawn as being drawn to non-elected subject matter.

Claim 94 has been amended to be rewritten in an independent format and to delete non-elected subject matter.

Applicants reserve the right to prosecute non-elected subject matter in one or more other applications.

No new matter has been introduced with the instant amendments to the claims. Entry thereof is respectfully requested.

No claim fee is believed to be due.

II. REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH (NEW MATTER REJECTION)

Claims 63 and 66-93 are rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement (New Matter Rejection).

Applicants respectfully submit that the rejection is moot in view of cancellation of claims 63 and 66-93.

III. REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH (WRITTEN DESCRIPTION REJECTION)

Claims 63 and 66-93 are rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement (Written Description Rejection).

Applicants respectfully submit that the rejection is moot in view of cancellation of these claims.

IV. REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH (ENABLEMENT REJECTION)

Claims 63 and 66-93 are rejected under 35 U.S.C. 112, first paragraph as being allegedly non-enabling for any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Applicants respectfully submit that the rejection is moot in view of cancellation of claims 63 and 66-93.

V. THE REJECTION UNDER 35 U.S.C. § 102 OVER SEGREST

Claims 63, 66-86 and 88-93 are rejected under 35 U.S.C. 102(a,b,e) as being anticipated by Segrest *et al.* (US Patent No. 4,643,988).

Applicants respectfully submit that the rejection is moot in view of cancellation of these claims.

VI. THE REJECTION UNDER 35 U.S.C. § 103 OVER SEGREST AND ISLIKER

Claims 63 and 66-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Segrest *et al.* (US Patent No. 4,643,988) and Isliker *et al.* (US Patent No. 5,089,602).

Applicants respectfully submit that the rejection is moot in view of cancellation of these claims.

VII. NONSTATUTORY DOUBLE PATENTING

A. US Patent Application Serial Nos. 10/937,767, 10/801,897, 09/865,989 and 10/099,574.

Claims 63 and 66-93 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over:

claims 1, 19-21, 28, 36, 41, 43-46, 53 and 56-57 of copending application Serial No. 10/937,767;

claims 53-83 of copending application Serial No. 10/801,897;

claims 1-52 of copending application Serial No. 09/865,989; and

claims 1-55 of copending application Serial No. 10/099,574.

Applicants respectfully submit that the rejection is moot in view of cancellation of claims 63 and 66-93.

B. US Patent Application Serial Nos. 10/283,599 and 10/099,836

Claims 63, 66-101, 103, 104 and 110 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-68 of copending application Serial No. 10/283,599 and claims 1-56 of copending application Serial No. 10/099,836.

Separate response is given below regarding each piece of art cited by the Examiner.

1. US Patent No. 6,844,327 (US Application Serial No. 10/283,599)

Claims 63, 66-101, 103, 104 and 110 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-68 of copending application Serial No. 10/283,599. It is respectfully submitted that the application Serial No. 10/283,599 has issued as a US Patent No. 6,844,327 on January 18, 2005 (hereinafter, "the '327 patent"). Applicants respectfully submit that the rejection is moot with respect to claims 63 and 66-93 in view of cancellation of these claims. With respect to claims 94-101, 103, 104 and 110, this rejection is traversed. Reconsideration is respectfully requested.

Obviousness-type double patenting is a judicially created doctrine intended to prevent improper timewise extension of the patent right by prohibiting the issuance of claims in a second patent which are not "patentably distinct" from the claims of a first patent. *See In re Braat*, 19 U.S.P.Q.2d 1289, 1291-92 (Fed. Cir. 1991). It is respectfully submitted that claims 1-68 of the '327 patent are patentably distinct from claims 94-101, 103, 104 and 110 of the instant application for the following reasons. The Patent Office states that the '327 patent "claims pharmaceutical compositions comprising ApoA-I agonist peptide-lipid complexes", as instantly claimed. The claims of the '327 patent, in fact, recite *nucleotide sequences* that *encode* ApoA-I agonist peptide compounds. It is well-established law that "the comparison can be made only with what invention is *claimed* in the earlier patent, paying careful attention to the rules of claim interpretation to determine what invention a claim *defines* and not looking to the claim for anything that happens to be mentioned in it as though it were a prior art reference." *See, e.g., General Foods Corp.*, 23 U.S.P.Q.2d 1839, 1845 (Fed. Cir. 1992). As claims 1-68 of the '327 patent are patentably distinct from claims 94-101, 103, 104 and 110 of the instant application, the imposed double patenting rejection is improper and should be withdrawn.

2. US Application Serial No. 10/099,836

Claims 63, 66-101, 103, 104 and 110 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-56 of US Patent Application Serial No. 10/099,836. Applicants respectfully submit that the rejection is

moot with respect to claims 63 and 66-93 in view of cancellation of these claims. With respect to claims 94-101, 103, 104 and 110, Applicants respectfully request that the rejection be held in abeyance until either of the applications is allowed. *See* MPEP 804(I)(B).

C. U.S. Patent Nos. 6,573,239, 6,265,377, 6,046,166 and 6,037,323

Claims 63 and 66-93 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over:

claims 1-34 of US Patent No. 6,573,239;

claims 1-48 of US Patent No. 6,265,377;

claims 1-49 of US Patent No. 6,046,166; and

claims 1-54 of US Patent No. 6,037,323.

Applicants respectfully submit that the rejection is moot in view of cancellation of claims 63 and 66-93.

D. U.S. Patent Nos. 6,753,313, 6,716,816, 6,630,450, 6,602,854, 6,518,412, 6,376,464, 6,329,341 and 6,004,925

Claims 63, 66-101, 103, 104 and 110 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over:

claims 1-48 of US Patent No. 6,753,313;

claims 1-58 of US Patent No. 6,716,816;

claims 1-36 of US Patent No. 6,630,450;

claims 1-38 of US Patent No. 6,602,854;

claims 1-9 of US Patent No. 6,518,412;

claims 1-21 of US Patent No. 6,376,464;

claims 1-21 of US Patent No. 6,329,341; and

claims 1-58 of US Patent No. 6,004,925.

Separate response is given below regarding each piece of art cited by the Examiner.

1. **U.S. Patent No. 6,753,313**

Claims 63, 66-101, 103, 104 and 110 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-48 of US Patent No. 6,753,313. Applicants respectfully submit that the rejection is moot with respect to claims 63 and 66-93 in view of cancellation of these claims. With respect to claims 94-101, 103, 104 and 110, without acquiescing with the propriety of the rejection and in order to expedite prosecution, Applicants respectfully request that the rejection be withdrawn in view of the Terminal Disclaimer and fee filed herewith.

2. **US Patent No. 6,716,816**

Claims 63, 66-101, 103, 104 and 110 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-58 of US Patent No. 6,716,816. Applicants respectfully submit that the rejection is moot with respect to claims 63 and 66-93 in view of cancellation of these claims. With respect to claims 94-101, 103, 104 and 110, without acquiescing with the propriety of the rejection and in order to expedite prosecution, Applicants respectfully request that the rejection be withdrawn in view of the Terminal Disclaimer and fee filed herewith.

3. **US Patent No. 6,630,450**

Claims 63, 66-101, 103, 104 and 110 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-36 of US Patent No. 6,630,450 (hereinafter, "the '450 patent"). Applicants respectfully submit that the rejection is moot with respect to claims 63 and 66-93 in view of cancellation of these claims. With respect to claims 94-101, 103, 104 and 110, this rejection is traversed. Reconsideration is respectfully requested.

Applicants respectfully submit that claims 1-36 of the '450 patent are patentably distinct from claims 94-101, 103, 104 and 110 of the instant application as drawn to a method of treating a disorder associated with dyslipidemia using apolipoprotein A-I peptides or peptide analogs *versus* a pharmaceutical composition comprising an ApoA-I-lipid complex. As such the two sets of claims are patentably distinct. *See, General Foods Corp.*, 23 U.S.P.Q.2d 1839, 1845 (Fed. Cir. 1992), *supra*. Accordingly, the imposed double patenting rejection is improper and should be withdrawn.

4. **US Patent No. 6,602,854**

Claims 63, 66-101, 103, 104 and 110 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-38 of US Patent No. 6,602,854. Applicants respectfully submit that the rejection is moot with respect to claims 63 and 66-93 in view of cancellation of these claims. With respect to claims 94-101, 103, 104 and 110, without acquiescing with the propriety of the rejection and in order to expedite prosecution, Applicants respectfully request that the rejection be withdrawn in view of the Terminal Disclaimer and fee filed herewith.

5. **US Patent No. 6,518,412**

Claims 63, 66-101, 103, 104 and 110 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of US Patent No. 6,518,412 (hereinafter, "the '412 patent"). Applicants respectfully submit that the rejection is moot with respect to claims 63 and 66-93 in view of cancellation of these claims. With respect to claims 94-101, 103, 104 and 110, this rejection is traversed. Reconsideration is respectfully requested.

It is respectfully submitted that claims 1-9 of the '412 patent are patentably distinct from claims 94-101, 103, 104 and 110 of the instant application for the following reasons. The Patent Office states that the '412 patent "teach pharmaceutical compositions comprising ApoA-I agonist peptide-lipid complexes", as instantly claimed. The claims of the '412 patent, in fact, are drawn to nucleotide sequences that *encode* ApoA-I agonist peptide compounds. As such, the subject matter of claims in the cited art is distinct from that as instantly claimed. *See, General Foods Corp.*, 23 U.S.P.Q.2d 1839, 1845 (Fed. Cir. 1992), *supra*. As claims 1-9 of the '412 patent are patentably distinct from claims 94-101, 103, 104 and 110 of the instant application, the imposed double patenting rejection is improper and should be withdrawn.

6. **US Patent No. 6,376,464**

Claims 63, 66-101, 103, 104 and 110 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of US Patent No. 6,376,464. Applicants respectfully submit that the rejection is moot with respect to claims 63 and 66-93 in view of cancellation of these claims. With respect to claims 94-101, 103, 104 and 110, without acquiescing with the propriety of the rejection and in order to expedite prosecution, Applicants respectfully request that the rejection be withdrawn in view of the Terminal

Disclaimer and fee filed herewith.

7. **US Patent No. 6,329,341**

Claims 63, 66-101, 103, 104 and 110 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of US Patent No. 6,329,341 (hereinafter, "the '341 patent"). Applicants respectfully submit that the rejection is moot with respect to claims 63 and 66-93 in view of cancellation of these claims. With respect to claims 94-101, 103, 104 and 110, this rejection is traversed. Reconsideration is respectfully requested.

Applicants respectfully submit that Claims 1-21 of the '341 patent are patentably distinct from Claims 1, 3-9, 12-16, 18 and 37 of the instant application as drawn to a method of treating septic shock using apolipoprotein A-I peptides or peptide analogs *versus* a pharmaceutical composition comprising an ApoA-I-lipid complex. As such the two sets of claims are patentably distinct. *See, General Foods Corp.*, 23 U.S.P.Q.2d 1839, 1845 (Fed. Cir. 1992), *supra.* Accordingly, the imposed double patenting rejection is improper and should be withdrawn.

8. **US Patent No. 6,004,925**

Claims 63, 66-101, 103, 104 and 110 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-58 of US Patent No. 6,004,925. Applicants respectfully submit that the rejection is moot with respect to claims 63 and 66-93 in view of cancellation of these claims. With respect to claims 94-101, 103, 104 and 110, without acquiescing with the propriety of the rejection and in order to expedite prosecution, Applicants respectfully request that the rejection be withdrawn in view of the Terminal Disclaimer and fee filed herewith.

CONCLUSION

In light of the above amendments and remarks, Applicants respectfully submit that claims 94-101, 103, 104 and 110 satisfy all the criteria for patentability and request that the Patent Office consider this application with a view towards allowance.

The Commissioner is hereby authorized to charge any required fee(s), including extension of time fees under 37 C.F.R. § 1.17, or credit any overpayment, to Jones Day Deposit Account No. 50-3013 (referencing Attorney Docket No. 9196-031-999).

Respectfully submitted,

Date: November 15, 2005

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